REMARKS/ARGUMENTS

This is a preliminary amendment in a RCE application. The Office Action mailed December 7, 2005 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. Claims 32-56 stand withdrawn from consideration as a result of a response to a restriction requirement. Claims 3, 4, 5, 13, 16, 17, 22, 23, 24, 29, 30, and 31 have been cancelled. The claims presented for examination are: claims 1-2, 6-12, 14-15, 18-21, and 25-28.

35 USC 101 Rejection

On page 2 of the Office Action mailed December 7, 2005, claims 11-12, 19-21, and 25-28 were rejected under 35 U.S.C. 101 as directed to non-statutory subject matter.

Applicants have amended claims 11-12, 19-21, and 25-28 using the terminology "adapted to" suggested by the Examiner. Applicants believe they have overcome the rejection under 35 U.S.C. 101 and that a full and complete response to the 35 U.S.C. 101 rejection in the Office Action mailed December 7, 2005 has been provided.

35 USC 112 Rejection

On pages 2 and 3 of the Office Action of the Office Action mailed December 7, 2005, claims 6, 8-12, 19, and 25-28 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claim 8 was rejected as indefinite in that it claims elements of the combination (device) but only the electrode array is being claimed per the preamble. Applicants have amended claim 8 by adding the element, "including a device for transferring a visual image signal" to make the claim definite.

Claims 6, 9, 12, and 21 were rejected as indefinite in that they lack sufficient structure to further limit the invention. Applicants have amended claims 6, 9, 12, and 21 by adding structure to make the claims definite.

Claims 10, 19, and 26 were rejected as partly redundant in regards to the composition of the substrate. Applicants have amended claims 10, 19, and 26 to include structure to make the claims definite. The terminology "composed entirely of poly(dimethylsiloxane)" is part of the original element in the base claims.

Claim 25 was rejected as indefinite in that it calls for the implant to consist of a substrate, however additional structure exists (electrodes). Applicants have amended claim 25 to change the term consisting of to comprising to make the claim definite.

Claims 26-28 were rejected as indefinite in that the preambles refer to the combination (system) but only the electrode array is being claimed. Applicants have amended Claims 26-28 to clarify the claims are an, "electrode array for an artificial vision system" to make the claims definite.

Applicants believe they have overcome the rejections under 35 U.S.C. 112 and that a full and complete response to the 35 U.S.C. 112 rejections in the Office Action mailed December 7, 2005 has been provided.

35 USC 103 Rejection

On pages 2 and 3 of the Office Action of the Office Action mailed December 7, 2005, claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the primary Edell reference (U.S. 5,476,494) in view of the secondary Pinchuk reference (U.S. 5,741,331).

Applicants believe that amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 are patentable. The inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,

148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include the following:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

The differences between the primary Ebell reference and Applicants' invention includes the fact that various elements of amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 are not found in the primary Ebell reference.

The Edell Reference

The Edell reference shows a cantilever 40 with an encapsulation layer 24 of silicone material encapsulating the cantilever 40. The cantilever 40 encapsulated by the encapsulation layer 24 is illustrated in FIG. 3 of the Edell reference. A copy of FIG. 3 of the Edell reference is provided below with inserts added that identify the cantilever 40 and the encapsulation layer 24.

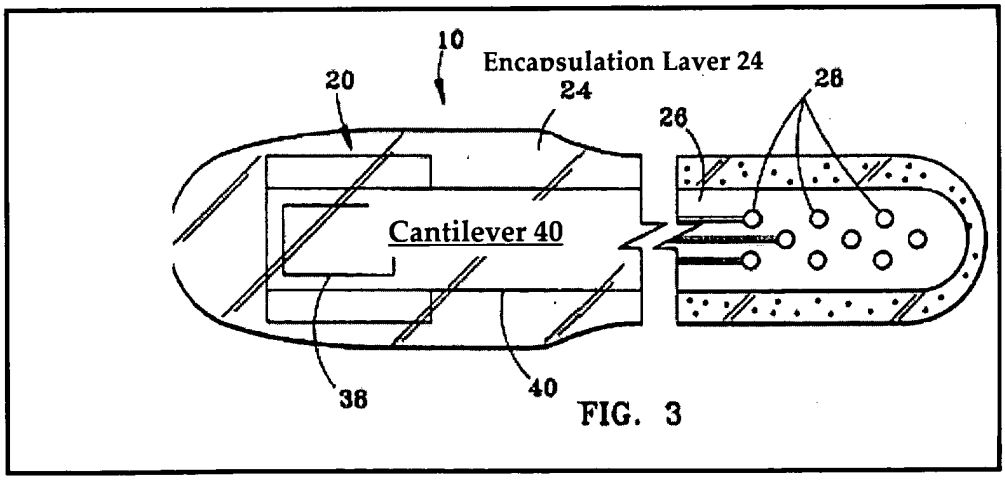

FIG. 3

The fact that the Edell reference shows a cantilever 40 is provided by the statements in the Edell reference which describes a cantilever 40 made of "silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials which exhibit some flexibility" (Col. 4, lines 45-47 of the Edell reference).

The fact that the Edell reference shows an encapsulation layer 24 is provided by the statements in the Edell reference which specifically state, "encapsulation layer 24 surrounds the cantilever structure 40" and the encapsulation layer 24 is "preferably of silicone material" (Col. 5, lines 62-64 of the Edell reference).

Claim Elements Missing From the Edell Reference

The Edell reference does not show Applicants' claim elements, "a .... substrate composed entirely of ..... flexible and stretchable polymer that has the ability to conform ....." (All of the Independent Claims - Claims 1, 18, and 25) In addition, the Edell reference does not show Applicants' claim elements, "micro-stimulator electrodes embedded in said conformable polymer substrate wherein said conformable substrate composed entirely of a flexible and stretchable polymer provides the support for said micro-stimulator electrodes." (Claims 1, 18, and 25)

A "substrate" is not the same as an "encapsulation layer." The two structural elements perform different functions. The "substrate" provides support; whereas, the "encapsulation layer" covers and protects what is encapsulated. Applicants' claims include the structural limitations that the "substrate composed entirely of a flexible and stretchable polymer provides the support for said micro-stimulator electrodes." In the Edell reference the cantilever 40 provides the support. The Edell reference cantilever 40 is not a flexible and stretchable polymer that has the ability to conform as defined in Applicants' claims.

Also, in the Edell reference the encapsulation layer 24 strictly covers and protects the cantilever 40. The Edell reference encapsulation layer 24 does provide support as defined in Applicants' claims.

Applicants point out that "Silicon" is well known as a material used as the substrate for an electronic device; however, "poly(dimethylsiloxane) or silicone" has not been known as a material used for a substrate support for an electronic device. "Silicone" is best known as the material used in breast implants. The article, "What is Silicone?" in www.silicone-review.gov.uk/silicone, provides the following definitions:

> "Silicon is the second most abundant element in the earth's crust, comprising around 28% of it. It is not found in its elemental form but occurs mainly as oxides and silicates. In contrast to carbon, silicon-silicon bonds are uncommon. Natural silicon-carbon bonds are extremely rare but they can be created synthetically."

> "Silicones are synthetic polymers and are not therefore found naturally. They have a linear, repeating silicon-oxygen backbone akin to silica. However, organic groups attached directly to the silicon atoms by carbon-silicon bonds prevent formation of the three-dimensional network found in silica. These types of compound are also known as polyorganosiloxanes. Certain organic groups can be used to link two or more of these silicon-oxygen backbones and the nature and extent of this crosslinking enables a wide variety of products to be manufactured. The most important materials used in medical implants are fluids, gels and rubbers (elastomers) whose physical and chemical properties include, amongst others, a high degree of chemical inertness, thermal stability and resistance to oxidation."

> "Silicone gels have lightly cross-linked polysiloxane networks, swollen with PDMS fluid to produce a cohesive mass. The PDMS fluid is not chemically bound to the crosslinked network but is retained only by physical means, as water is in a sponge, and there is a tendency for the fluid to 'bleed.' The degree of cross-linking and amount of fluid affects the physical properties of the gel and the rate at which fluid 'bleeds' from it. Once suitably

cross-linked, silicone gels retain their form without external containment."

Applicants' claimed invention is unobvious and there could be no legitimate combination of the secondary Pinchuk reference with the primary Ebell reference to support a 35 USC §103(a) rejection. In the Ebell reference the silicone encapsulation layer 24 is strictly used for encapsulating the support cantilever 40. The secondary Pinchuk reference is strictly directed to "vascular grafts, endoluminal grafts, intraocular lenses, finger joints, indwelling catheters, pacemaker lead insulators, breast implants, heart valves, knee and hip joints, vertebral disks, meniscuses, tooth liners, plastic surgery implants, tissue expanders, drug release membranes, subcutaneous ports, injection septums, etc." (Col. 1, lines 34-40 of the Pinchuk reference) The Pinchuk reference is not directed to an electronic device and does not take the problems of an electronic device or the background of electronic devices into consideration.

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The proposed combination of the Ebell reference and the Pinchuk reference does not support a rejection of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 under 35 USC 103, and the rejection should be withdrawn.

Secondary Considerations

The invention of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 has obtained commercial success and recognition by peers. An October 14,

2004 News Release by the Lawrence Livermore National Laboratory, titled "Livermore scientists join DOE consortium and private company to develop artificial retina," included the statements below. A copy of the Lawrence Livermore National Laboratory News Release is attached. A similar New Release by U. S. Department of Energy, titled "DOE Labs, Universities and Second Sight Partner to Speed Development of 'Artificial Retina' Restoring Sight through Science," also included the statements. A copy of the U. S. Department of Energy News Release is attached.

> A Department of Energy (DOE) consortium of national laboratories including Lawrence Livermore National Laboratory and universities today signed an agreement with Second Sight Medical Products Inc. to jointly develop technology that could restore sight to those who have lost vision later in life. The Cooperative Research and Development Agreement (CRADA) allows Second Sight, of Sylmar, Calif. to obtain a limited exclusive license for inventions developed during the DOE Retinal Prosthesis Project. .....
>
> "The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Energy Secretary Spencer Abraham said. "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see. ....
>
> Engineers from LLNL's Center for Micro- and Nanotechnology specifically are developing a flexible silicone implant (microelectrode array) that sits on the surface of the retina. The electrode array can contact delicate retinal tissue without damaging it.
>
> The implantable retinal prosthesis is based on a system that converts a video camera signal into a stimulation pattern that is applied directly to the intra-ocular retinal surface. This is referred to as an epiretinal implant - the device is in contact with the surface of the retina. Visual signals are captured by a small video camera in the eyeglasses of the blind person and processed through a microcomputer worn on a belt.
>
> Although the device will not restore full vision, it is expected to provide enough optical resolution for patients to read and recognize fine shapes.
>
> LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina.

> "PDMS has the look and feel of thin plastic food wrap," said Livermore's principal investigator, Courtney Davidson. "Yet it's biocompatible, making it a good candidate material for long-term implants."

The proposed combination of the Ebell reference and the Pinchuk reference does not produce the invention of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28. Further, secondary considerations (1) that the Cooperative Research and Development Agreement (CRADA) allows Second Sight, of Sylmar, Calif. to obtain a limited exclusive license for inventions developed during the DOE Retinal Prosthesis Project, (2) that LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina, and (3) that Energy Secretary Spencer Abraham said "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see," should be taken into account in deciding the obviousness or nonobviousness of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28. Applicants request that the rejection of Applicants' amended claims 1, 2, 6-12, 14, 15, 18-21 and 25-28 under 35 USC 103(a) be withdrawn.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated December 7, 2005 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,

Eddie E. Scott
Attorney for Applicant
Registration No. 25,220
Tel. No. (925) 424-6897

Livermore, California
Dated: March 2, 2006

News Release

Contact: Anne Stark
Phone: (925) 422-9799
E-mail: stark8@llnl.gov

FOR IMMEDIATE RELEASE
Date: October 14, 2004
NR-04-10-03

Livermore scientists join DOE consortium and private company to develop artificial retina

CHICAGO, Ill. - A Department of Energy (DOE) consortium of national laboratories including Lawrence Livermore National Laboratory and universities today signed an agreement with Second Sight Medical Products Inc. to jointly develop technology that could restore sight to those who have lost vision later in life.

Researcher at LLNL checks the circuit continuity in a flexible polymer microelectrode array for possible implantation in a test subject's eye.

The Cooperative Research and Development Agreement (CRADA) allows Second Sight, of Sylmar, Calif. to obtain a limited exclusive license for inventions developed during the DOE Retinal Prosthesis Project.

"The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Energy Secretary Spencer Abraham said. "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see. This agreement between the DOE laboratories and the private sector will facilitate transfer of many aspects of DOE technology to a clinical device that has the potential of restoring sight to millions of blind individuals."

An artificial retina could restore vision to millions of people suffering from eye diseases such as macular degeneration (the leading cause of blindness in people over 60), retinitis pigmentosa (the leading cause of blindness in people under 50), or those who are legally blind due to the loss of photoreceptor function.

Lawrence Livermore partnered with four other national laboratories, three universities and Second Sight on the project.

Engineers from LLNL's Center for Micro- and Nanotechnology specifically are developing a flexible silicone implant (microelectrode array) that sits on the surface of the retina. The electrode array can contact delicate retinal tissue without damaging it.

The implantable retinal prosthesis is based on a system that converts a video camera signal into a stimulation pattern that is applied directly to the intra-ocular retinal surface. This is referred to as an epiretinal implant - the device is in contact with the surface of the retina. Visual signals are captured by a small video camera in the eyeglasses of the blind person and processed through a microcomputer worn on a belt.

Although the device will not restore full vision, it is expected to provide enough optical resolution for patients to read and recognize fine shapes.

LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina.

"PDMS has the look and feel of thin plastic food wrap," said Livermore's principal investigator, Courtney Davidson. "Yet it's biocompatible, making it a good candidate material for long-term implants."

Partners in the project include Oak Ridge, Argonne, Sandia and Los Alamos national laboratories, the University of California, Santa Cruz, the University of Southern California Doheny Eye Institute and North Carolina State University.

Project leader Dr. Mark Humayun of USC has shown that electrical stimulation of the viable retinal cells can result in visual perception. These findings helped spark the worldwide effort to develop a retinal prosthesis device.

The first patient to receive a prototype implant in 2002 was able to see large letters and to differentiate between a cup, a plate and a knife after being blind for more than 50 years. To date, six volunteers have received implants of a micro-electronic device that rests on the surface of the retina to perform the function of normal photoreceptive cells.

The artificial retina technology was featured today at the department's "What's Next Expo," an event designed to showcase the newest, most innovative, cutting-edge scientific and technological advances to interest young people in pursuing careers in math and science.

Second Sight was founded in 1998 to create a retinal prosthesis to provide sight to patients blinded from outer retinal degenerations.

Founded in 1952, Lawrence Livermore National Laboratory is a national security laboratory, with a mission to ensure national security and apply science and technology to the important issues of our time. Lawrence Livermore National Laboratory is managed by the University of California for the National Nuclear Security Administration/U.S. Department of Energy.

U.S. DEPARTMENT OF ENERGY

October 14, 2004

DOE Labs, Universities and Second Sight Partner to Speed Development of "Artificial Retina"
Restoring Sight through Science

CHICAGO, IL – In an effort to speed the design and development of an artificial retina that could potentially help millions of people blinded by retinal diseases, Secretary of Energy Spencer Abraham announced today that five Department of Energy (DOE) national laboratories, a private company and three universities have signed agreements to form a research partnership.

The goal of the agreements signed today is to advance the science, technology and clinical success of the field of artificial sight using the facilities and resources of DOE's national laboratories.

At today's announcement in Chicago, the first patient to receive a prototype implant in 2002 described what it was like being able to "see" large letters and to differentiate between a cup, a plate and a knife after being blind for over 50 years. To date, six volunteers have received implants of a micro-electronic device that rests on the surface of the retina to perform the function of normal photoreceptive cells. The artificial retina technology was featured at the department's "What's Next Expo," an event designed to showcase the newest, most innovative, cutting-edge scientific and technological advances to interest young people in pursuing careers in math and science.

"The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Secretary Abraham said. "This project is one such example where biology, physics, and engineering have joined forces to deliver a capability that will enable blind people to see. This agreement between the DOE laboratories and the private sector will facilitate transfer of many aspects of DOE technology to a clinical device that has the potential of restoring sight to millions of blind individuals."

The agreements allow Second Sight Medical Products Inc. based in Sylmar, Calif., to obtain a limited exclusive license for inventions developed during the artificial retina project. Under the research agreements, the institutions will jointly share intellectual property rights and royalties from their research. This will speed progress by freeing the researchers to share details of their work with their collaborators.

The artificial retina could help those blinded by age-related macular degeneration or retinitis pigmentosa where neural wiring from the eye to brain is intact, but the eyes lack photoreceptor activity. The artificial retina is a device that captures visual signals and sends them to the brain in the form of electrical impulses. The device is a miniature disc that contains an electrode array that can be implanted in the back of the eye to replace a damaged retina. Visual signals are captured by a small video camera in the eyeglasses of the blind person and processed through a microcomputer worn on a belt. The signals are transmitted to the electrode array in the eye. The array stimulates optical nerves, which then carry a signal to the brain. The first prototype implants contain 16 electrodes. The next prototype, with 50-100 electrodes, is in preclinical trials. The project's "next generation" device would have 1,000 electrodes and hopefully would allow the user to see images.

The Department of Energy-supported project is a collaboration of DOE national laboratories, universities and the private sector:

Oak Ridge National Laboratory and the University of Southern California Doheny Eye Institute are leading the multi-laboratory effort. Oak Ridge's research includes developing better electrodes and fabrication techniques and studying the long-term stability of the device once it is implanted.

Argonne National Laboratory scientists, in collaboration with Second Sight, are using their patented ultrananocrystalline diamond technology to make the implant biocompatible with the surrounding ocular tissue.

Lawrence Livermore National Laboratory is developing a thin, flexible implant that can conform to the curved shape of the retina.

A **Los Alamos National Laboratory** team is developing advanced optical imaging techniques. They are providing a better understanding of how the prosthesis works, by mapping the interaction between the brain and retina.

Sandia National Laboratories researchers are developing advanced electrodes using MEMS (micro-electro-mechanical systems) research.

The University of Southern California Doheny Eye Institute provides medical direction of the project and performs clinical testing of the implants.

North Carolina State University is performing electrical and thermal modeling of the device to help determine how much energy can be used to stimulate the remaining non-diseased cells.

University of California, Santa Cruz work includes wireless communication technology to provide the link between the camera and the implant.

Second Sight created the prototype device that is currently in testing. Second Sight will integrate DOE technology into product designs that will eventually move on to clinical trials.

Using the unique resources of the DOE national laboratories in materials sciences, microfabrication, microelectrode construction, photochemistry and computer modeling, the project's goal is to construct the device, capable of restoring vision, with materials that will last for the lifetime of a blind person. Although images will initially be captured by a camera housed in an eyeglass frame, researchers hope eventually to develop a completely implanted system for this purpose. DOE's effort is focused on developing high-grade microelectrodes and testing their long term biological effects, developing electrode and platform materials that are pliable and will last a lifetime within the eye, constructing a completely wireless device for clinical use and performing the computational modeling of long-term retinal stimulation.

The Energy Department's Office of Science plans to fund the artificial retina project at $20 million over the next three years. The department funds the project as part of its medical applications technology program. DOE and its predecessor agencies have been in the forefront of imaging sciences including clinical imaging in nuclear medicine and imaging atoms at synchrotron light sources. The National Institutes of Health and the National Science Foundation are also supporting the project.